K063081

1/2

TORNIER

Summary of Safety and Effectiveness information
510(k) Premarket Notification – Aequalis Resurfacing Head

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

NOV - 9 2006

1) Device name

Trade name:	**Aequalis Shoulder System**
Common name:	Total shoulder prosthesis
Classification name:	888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis

2) Submitter

Tornier
B.P. 11 - Rue Doyen Gosse
38330 Saint Ismier - France

3) Company contact

Tornier
Mrs Mireille Lémery
Regulatory affairs Manager
161, rue Lavoisier - Montbonnot
38334 Saint Ismier Cedex - France
Tel: 00 33 4 76 61 38 98
Fax: 00 33 4 76 61 35 33
e-mail : mireille.lemery@tornier.fr

4) Classification

Device class:	Class II
Classification panel:	Orthopedic
Product code:	HSD

5) Equivalent / Predicate device

Aequalis Shoulder System, Tornier, K952928, K043077, K060209
DePuy Global Shoulder System, DePuy Orthopaedics, Inc K060874

6) Device description

The usual goal of total shoulder and hemi-arthroplasty replacement of the shoulder is to restore the shoulder joint to its best working condition and to reduce or eliminate pain. The Aequalis Shoulder System is intended to accomplish these goals.
It consists of a humeral stem and a humeral head. With these systems the natural glenoid elements of the shoulder may be conserved or replaced as warranted by the state of disease or injury. Thus the Aequalis Shoulder Fracture System is intended for use as a total shoulder replacement system, or as a hemi-shoulder.

TORNIER SAS
161 rue Lavoisier. Montbonnot. 38334 SAINT-ISMIER Cedex. France
Tél. : 33(0)4 76 61 35 00 Fax : 33 (0)4 76 61 35 33 www.tornier.com

The modular nature of the system allows for the later conversion of a primary hemi-arthrosplasty to a total shoulder replacement.

The present device submission corresponds to the addition of a new glenoid model to the current cleared model. The new glenoid model is a modification of the shape of the current model. The technological characteristics (materials, manufacturing, sterilization, sizing and indications) of the new glenoid of the Aequalis Shoulder System are similar or identical to the predicate devices.

7) Materials

The glenoid component is made of ultra high molecular weight polyethylene (UHMWPE) according to ISO standard 5834-2.

8) Indications

Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability caused by:

- Degenerative pathologies: arthrosis, rheumatoid arthritis, post-traumatic arthrosis. Primary and secondary necrosis of the humeral head
- Displaced 4-part upper humeral fracture
- Humeral head fracture

Other pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable.
Revision surgery when other treatments or devices have failed.

TORNIER SAS
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

TORNIER S.A.S
% Ms. Mireille Lemery
Regulatory Affairs Manager
161 rue Lavoisier - Montbonnot
38334 Saint –Ismier Cedex
France

NOV - 9 2006

Re: K063081
Trade/Device Name: Aequalis Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/ polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSD
Dated: September 5, 2006
Received: October 10, 2006

Dear Ms. Lemery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K063081 1/1

510(k) Number (if known):

Device Name: Aequalis Shoulder System

Indications For Use:

Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability caused by:

- Degenerative pathologies: arthrosis, rheumatoid arthritis, post-traumatic arthrosis. Primary and secondary necrosis of the humeral head
- Displaced 4-part upper humeral fracture
- Humeral head fracture

Other pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable

Revision surgery when other treatments or devices have failed.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063081